UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DINA ANDREN and SIDNEY BLUDMAN, individually and on behalf of other members of the general public similarly situated,

Plaintiffs,

v.

ALERE, INC., a Delaware corporation ALERE HOME MONITORING, INC., a Delaware Corporation; ALERE SAN DIEGO, INC., a Delaware corporation,

Defendants.

CASE NO. 16cv1255-GPC(NLS)

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO STRIKE

[Dkt. No. 29.]

Before the Court is Defendants' motion to strike portions of the first amended complaint. (Dkt. No. 29.) An opposition and reply were filed. (Dkt. Nos. 37, 39.) Based on the reasoning below, the Court GRANTS in part and DENIES in part Defendants' motion to strike.

/ / / /

Background

On May 26, 2016, Plaintiffs Dina Andren and Sidney Bludman filed a purported class action complaint against Defendants Alere, Inc., Alere Home Monitoring, Inc. and Alere San Diego, Inc. ("Defendants"). After the Court granted Defendants' motion to dismiss with leave to amend, (Dkt. No. 19), on October 3, 2016, Plaintiffs Dina Andren, Sidney Bludman, Virginia Cioffi, Bernard Falk, Jeanette Kerzner-Green, Carol Montalbano and Donald Rigot filed a purported first amended class action complaint against Defendants for unlawfully, deceptively and misleadingly engaging in the advertising, marketing and sales of the "INRatio PT/INR Monitors," "INRatio PT/INR Test Strips," "INRatio2 PT/INR Monitors" and "INRatio2 PT/INR Test Strips" (collectively, "INRatio Products"). (Dkt. No. 21, FAC.) The FAC alleges sixteen causes of action for violations of (1) California's Consumer Legal Remedies Act ("CLRA"), Cal. Civil Code §§ 1750 *et seq.*; (2) California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200 *et seq*.; (3) fraud; (4) unjust enrichment; (5) Colorado Consumer Protection Act, Colo. Rev. Stat. §§ 6-1-101 *et seq.*; (6) breach of the implied warranty of merchantability, Colo. Rev. Stat. § 4-2-314; (7) Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, *et seq*.; (8) breach of the implied warranty of merchantability, Fla. Stat. §§ 672.314, *et seq*.; (9) Georgia Fair Business Practices Act, Ga. Code Ann. §§ 10-1-390, *et seq*.; (10) Georgia Uniform Deceptive Trade Practices Act, Ga. Code Ann. §§ 10-1-370, *et seq*.; (11) Maryland Consumer Protection Act, Md. Code Com. Law §§ 13-101, *et seq*.; (12) breach of the implied warranty of merchantability under Md. Code Com. Law § 2-314; (13) New York General Business Law, N.Y. Gen. Bus. Law § 349; (14) New York General Business Law, N.Y. Gen. Bus. Law § 350; (15) Pennsylvania Unfair Trade Practices and Consumer Protection Law, Pa. Stat. Ann. §§ 201-1, *et seq*.; and (16) breach of the implied warranty of merchantability, 13 Pa. Stat. Ann. § 2314. (Id.)

In the late 1990's Defendants' predecessor, HomoSense, Inc.[1], developed and manufactured the "INRatio products" which are electronic testing devices designed to assist patients who have been prescribed blood-thinners, such as warfarin, to monitor their blood clotting time at home. (Id. ¶¶ 19, 25.) The INRatio monitor, paired with the INRatio test strips are known as the "INRatio testing kit" (Id. ¶ 26.) The ability to monitor and test their blood-clotting times and adjust patients' blood-thinner dosages is critical as an inappropriate amount of blood-thinners can result in serious bodily injury and death. (Id. ¶ 2.)

The International Normalized Ratio ("INR") is a standardized metric used to determine the relative speed at which blood clots in a patient's body. (Id. ¶ 22.) "A patient's INR is calculated by comparing a patient's prothrombin time (the speed at which the patient's blood clots) against the normal mean prothrombin time (the average speed for bloodclotting in the general population). The resulting contrast between a patient's prothrombin time and the normal mean prothrombin time is the patient's "INR." (Id.) Doctors and patients use the INR to monitor the blood-clotting speed for patients who have been prescribed blood thinners to determine whether a patient should increase or decrease his/her dosage of blood thinners. (Id. ¶ 23.)

In October 2002, the FDA approved the INRatio testing kit for home use and sales began in 2003. (Id. ¶ 27.) The "INRatio2" testing kit was later developed and operated similarly to the INRatio testing kit. (Id. ¶ 28.)

The FAC alleges that sometime immediately after the INRatio products became available to the public, Defendants received numerous complaints about the INRatio products' efficacy and accuracy. (Id. ¶ 30.) Between 2002 and 2014, Defendants received over 18,000 complaints concerning malfunctions with the INRatio products, with at least three complaints resulting in deaths. (Id. ¶ 32.)

---

[1]In August 2007, Alere, Inc. (then known as Inverness Medical Innovaction, Inc.) purchased HomoSense, Inc. (Dkt. No. 1, Compl. ¶ 19.) In 2008, HomoSense, Inc. transferred its operations to Alere, Inc's facility in San Diego, California. (Id.) In 2013, HomoSense, Inc.'s operations were merged into the Alere San Diego corporate entity. (Id.)

In May 2005, after receiving numerous complaints about the INRatio products, the FDA conducted an inspection of Defendants' San Jose operations facility and following the inspection, the FDA sent a warning letter admonishing them for their failure to file Medical Device Reporting ("MDR") reports based on failing to report complaints about "discrepant lab results" and "generating clinically significant erroneous values." (Id. ¶¶ 34-35.) From May 15, 2006 through July 13, 2006, the FDA conducted another inspection of the San Jose facility and on November 29, 2006, the FDA sent Defendants another warning letter for numerous failure to comply with statutory regulations. (Id. ¶¶ 38. 39.)

On April 16, 2014, Defendants issued a voluntary "Class 1"[2] recall notice for the INRatio2 test strips, citing the disparity between INR results obtained with the INRatio2 system versus significantly higher INR results when re-testing was performed by an independent laboratory. (Id. ¶ 55.) Defendants' recall notice requested that customers immediately cease using the INRatio2 PT/INR test strips and instead use alternate methods to perform INR testing, including using the INRatio PT/INR test strips. (Id.) On December 5, 2014, Defendants issued another Class 1 voluntary recall letter for the INRatio PT/INR Monitor and INRatio2 PT/INR Monitor, as well as the INRatio PT/INR Test Strips. (Id. ¶¶ 63, 70.) The letter stated, "[i]n certain cases an INRatio PT/INR Testing kit may provide an INR result that is significantly lower than a result obtained using a laboratory INR system." (Id. ¶ 63.) The recall notice failed to state that the products were defective but instead stated that false results "can arise if [users] have certain medical conditions." (Id.)

After the instant complaint was filed on May 25, 2016, on July 11, 2016, Defendants issued a recall notice withdrawing all INRatio products from the market pursuant to direction by the FDA. (Id. ¶ 71.)

In September 2011, a study, later known as the Rocket AF trial, was published

---

[2]The FDA classifies Class 1 recalls as those involving use of products that causes serious adverse health consequences or death. (Dkt. No. 21, FAC ¶ 62.)

in the New England Journal of Medicine whose purpose was to compare the most commonly prescribed blood-thinner, warfarin, to a newer drug called rivaroxaban (also known as "Xarelto") to determine which drug was more effective in preventing strokes and embolism. (Id. ¶ 75.) During the study, some of the patient-participants took Xarelto while others took warfarin. (Id. ¶ 76.) The warfarin group had to constantly monitor their INRs and adjust their dosage as necessary. (Id.) The study determined that Xarelto was "noninferior" to warfarin and the findings ultimately led to FDA approval of Xarelto. (Id. ¶ 77.) After the April and December 2014 recalls, it was revealed that the warfarin participants used the INRatio products to monitor their INRs which has called the entire study into questions. (Id. ¶¶ 78, 79.) Data from blood samples from over 5000 participants of the Rocket AF trial revealed that the INR data collected using the INRatio products differed from test results from a third party laboratory. (Id. ¶ 79.) The makers of Xarelto, Johnson & Johnson, turned over this data to Defendants. (Id.) A letter dated December 10, 2015 and written by Sidney Wolfe, M.D., founder of the Public Citizen Health Research Group, and F.R Rosendaal, M.D., Ph.D., chair of the Department of Clinical Epidemiology at Lieden University Medical Center, to Stephen Ostroff, M.D., acting commissioner of the FDA, questioned the Rocket AF study based on the revelation that there may have been false readings to monitor the INR. (Id. ¶ 80, id. n. 24.)

Despite receiving numerous complaints from users and multiple warning letters from the FDA, notifying them that the results produced by the INRatio products differed from those produced by independent laboratories, Defendants continued selling the INRatio products and marketed and advertised them as "accurate," "convenient," "effective," "reliable," "optimal" and "safe. (Id. ¶ 3.) As a result, due to the erroneous results produced by the products, patients have been misled and have caused them to improperly adjust their blood-thinner dosages increasing the risk and likelihood of serious bodily injury or death. (Id. ¶ 4.)

A. Legal Standard on Federal Rule of Civil Procedure 12(f)

Rule 12(f) provides that the court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "The function of a 12(f) motion to strike is to avoid the expenditure of time and money that must arise from litigating spurious issues by dispensing with those issues prior to trial . . . ." Whittlestone, Inc. v. Handi–Craft Co., 618 F.3d 970, 973 (9th Cir. 2010) (quoting Fantasy, Inc. v. Fogerty, 984 F.2d 1524, 1527 (9th Cir. 1993), rev'd on other grounds 510 U.S. 517 (1994)).

"Motions to strike are 'generally disfavored because they are often used as delaying tactics and because of the limited importance of pleadings in federal practice.'" Cortina v. Goya Foods, Inc., 94 F. Supp. 3d 1174, 1182 (S.D. Cal. 2015) (quoting Rosales v. Citibank, 133 F. Supp. 2d 1177, 1180 (N.D. Cal. 2001)). As such, "motions to strike should not be granted unless it is clear that the matter to be stricken could have no possible bearing on the subject matter of the litigation." Colaprico v. Sun Microsys., Inc., 758 F. Supp. 1335, 1339 (N.D. Cal. 1991). "Courts will not grant motions to strike unless 'convinced that there are no questions of fact, that any questions of law are clear and not in dispute, and that under no set of circumstances could the claim or defense succeed.'" Novick v. UNUM Life Ins. Co. of America, 570 F. Supp. 2d 1207, 1208 (C.D. Cal. 2008) (quoting RDF Media Ltd. v. Fox Broad. Co., 372 F. Supp. 2d 556, 561 (C.D. Cal. 2005)). "When ruling on a motion to strike, this Court 'must view the pleading under attack in the light most favorable to the pleader." Id. (citing RDF Media Ltd., 372 F. Supp. 2d at 561).

"Immaterial matter is that which has no essential or important relationship to the claim for relief or the defenses being pleaded." Fantasy, Inc., 984 F.2d at 1527 (internal citations and quotations omitted). "Impertinent matter consists of statements that do not pertain, and are not necessary, to the issues in question." Id. (internal citations and quotations omitted). A pleading is scandalous if it "improperly casts a derogatory light on someone, most typically on a party to the action." Cortina, 94 F.

Supp. at 1182.

Matters outside the pleadings are not normally considered on a Rule 12(f) motion as "motions to strike are decided on the pleadings alone." Hanover Ins. Co. v. Ryan, 619 F. Supp. 2d 127, 132 (E.D. Pa. 2007) (citing N. Penn Transfer, Inc., v. Victaulic Co. of America, 859 F. Supp. 154, 158 (E.D. Pa. 1994)); Peterson v. Baloun, 715 F. Supp. 212, 214 (N.D. Ill. 1989); Index Fund, Inc. v. Hagopian, 107 F.R.D. 95, 100 (S.D.N.Y. 1985) ("In deciding a motion to strike, a court will not consider matters outside the pleadings, and well-pleaded facts will be accepted as true.").

"Matters may be stricken to reduce trial complication or if challenged allegations are so unrelated to plaintiff's claims to be unworthy of consideration as a defense and their presence in the pleading will prejudice the party seeking to strike matters." Ollier v. Sweetwater Union High School Dist., 735 F. Supp. 2d 1222, 1224 (S.D. Cal. 2010) (citing Fantasy, Inc., 984 F.2d at 1527). A motion to strike should be granted only if "the matter has no logical connection to the controversy at issue and may prejudice one or more of the parties to the suit." New York City Employees' Retirement Sys. v. Berry, 667 F. Supp. 2d 1121, 1128 (N.D. Cal. 2009) (quoting Rivers v. County of Marin, No. C 05-4251, 2006 WL 581096, at *2 (N.D. Cal. 2006). Where the moving party cannot adequately demonstrate such prejudice, courts frequently deny motions to strike "even though the offending matter literally [was] within one or more of the categories set forth in Rule 12(f)." Id.

In their motion, Defendants seek to strike paragraphs 74-80 of the FAC concerning the Rocket AF trial as immaterial, impertinent and potentially prejudicial. Plaintiffs disagree arguing the allegations concerning the Rocket AF trial directly goes to key issues in the case.

A. Immaterial and Impertinent

Defendants move to strike paragraphs 74 through 80 of the FAC as the allegations concerning the Rocket AF trial contained in these paragraphs are immaterial and impertinent. They argue that Plaintiffs do not assert that they were prescribed

Xarelto, took Xarelto or were ever harmed by Xarelto and do not allege that Defendants played any role or had any financial stake in the development, marketing or sale of Xarelto. Therefore, the allegations concerning the Rocket AF trial are immaterial and impertinent. Moreover, whether INRatio products yielded inaccurate results during the Rocket AF study and whether the allegedly inaccurate results played a role in the FDA's approval of Xarelto is not relevant to the claims in this case.

Plaintiffs oppose arguing that the allegations about the Rocket AF trial are relevant to whether INRatio Products are defective and whether Defendants knowingly misled patients and healthcare providers by omitting material information and falsely representing to them that the products were safe and reliable. In reply, citing to exhibits attached to their reply, Defendants argue that the Rocket AF study is not pertinent to the issues in the case because the Rocket AF trial used Defendants' first generation or INRatio PT/INR monitor and test strips. Since the seven named Plaintiffs allege they used the INRatio2 products, which did not come onto the market until after October 2007, the Rocket AF trial, using only INRatio products, is irrelevant.

By citing to and relying on exhibits attached to their reply, Defendants launch a factual attack on the allegations they seek to strike which is not proper on a Rule 12(f) motion. See Hanover Ins. Co., 619 F. Supp. 2d at 132. However, even if Defendants' argument that the Rocket AF trial is irrelevant because the participants of the trial used the INRatio PT/INR product, not the INRatio2 products that Plaintiffs purchased, were considered, the FAC alleges that when Defendants issued their voluntary recall notice on April 16, 2014 as to the INRatio2 test strips, users were directed to use alternate methods to perform INR testing "including substituting INRatio PT/INR test strips for the defective INRatio2 PT/INR test strips." (Dkt. No. 21, FAC ¶ 55.) "By directing users to substitute the INRatio PT/INR test strips for the defective INRatio2 PT/INR test strips, Defendants falsely and misleadingly represented to healthcare professional and consumers that the INRRatio PT/INR test strips worked properly, when in fact they caused false and erroneous results." (Id. ¶ 57.) Therefore,

even though Plaintiffs purchased the INRatio2 monitors and test strips, it is not clear whether they replaced the INRatio2 products for the INRatio PT/INR test strips after the recall.[3] Consequently, the Court cannot conclude that the Rocket AF trial has "no possible bearing on the subject matter of the litigation." See Colaprico, 758 F. Supp. at 1339.

Defendants also argue that timing of the trial and the alleged knowledge Defendants had of the false readings from the Rocket AF trial make the allegations immaterial since the reports of the alleged false readings did not occur until long after Plaintiffs purchased their products. The Court does not find their argument persuasive. First, Defendants improperly rely on matters outside the complaint to support their argument, and the Court declines to consider the exhibits. Second, the FAC alleges that after the April and December 2014, it was revealed that there were false INR readings during the Rocket AF study. Plaintiffs allege they purchased their INRatio2 product between January 2008 through April 30, 2015. Therefore, there is a plausible inference that Defendants learned about the false readings from the Rocket AF study before one or more of the Plaintiffs purchased their product. Therefore, on the face of the FAC, the Court cannot conclude that Defendants obtained knowledge about the false readings during the Rocket AF trial long after Plaintiffs purchased their products.

B. Prejudicial

Defendants further argue the allegations may be prejudicial to them because the allegations imply that they had a role in harming persons who have used Xarelto. Moreover, they will be prejudiced because Plaintiffs will seek discovery on these irrelevant issues at substantial cost to Defendants. (Dkt. No. 29 at 6.) Plaintiffs disagree arguing that Defendants' argument is based on innuendo and speculation.

Under the heading "The ROCKET AF Trial", the FAC alleges the "damage

[3]While five of the plaintiffs allege they were not aware of the recalls, (Dkt. No. 21, FAC ¶¶ 90, 116, 130, 138, 146), Bludman and Falk do not allege they were not aware of the recalls and may have complied with the recall instructions and substituted INRatio PT/INR test strips for the defective INRatio 2 PT/INR test strips.

caused by the INRatio Products' failures, Defendants' unlawful refusal to acknowledge or address those failures, and Defendants' continued manufacturing, marketing and selling of a dangerously defective product to unsuspecting consumers, extends beyond the harm suffered by individual users." (Dkt. No. 21, FAC ¶ 74.) This allegation creates a strong implication that Plaintiffs are alleging harm beyond themselves to include Xarelto users which are immaterial to the claims of this case. The allegation in paragraph 74 is prejudicial and not relevant to the issues in this case and should be stricken.

While the remaining allegations create an implication that were it not for the use of INRatio products used during the Rocket AF trial, Xarelto might not have received FDA approval, such an implication is not spurious as Defendants assert as it is a logical inference to be made based on the facts presented. Moreover, if the Court were to consider the documents attached to Defendants' reply, the inference that Xarelto might not have been approved by the FDA due to the use of INRatio products, is already part of the public record. (Dkt. No. 39, Ds' Reply, Ex. C at 34.) Thus, the Court denies Defendants' motion to strike paragraphs 75-80.

In sum, the Court GRANTS Defendants' motion to strike paragraph 74 and DENIES Defendants' motion to strike the remaining paragraphs 75-80.

Conclusion

Based on the above, the Court GRANTS in part and DENIES in part Defendants' motion to strike. The hearing set for January 20, 2017 shall be **vacated.**

IT IS SO ORDERED.

DATED: January 17, 2017

HON. GONZALO P. CURIEL
United States District Judge